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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/032,311

12/21/2001

Robert W. Doms

53893-5012-01

6825

34136

7590

02/23/2009

Pepper Hamilton LLP
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EXAMINER

PARKIN, JEFFREY S

ART UNIT

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1648

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/032,311	Applicant(s) DOMS ET AL.	
	Examiner Jeffrey S. Parkin	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8 and 51-56 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51-56 is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/30/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

Application No.: 10/032,311
Applicants: Doms, R. W, et al.

Docket No.: 53893-5012-01
Filing Date: 12/21/2001

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the amendment filed 30 October, 2008, wherein claim 2 was amended and new claims 51-56 introduced. Claims 1, 2, 5-8, and 51-56 are pending in the instant application.

37 C.F.R. § 1.98

The information disclosure statement filed 30 October, 2008, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 120 Benefit

Acknowledgement is hereby made of applicants' priority claims under 35 U.S.C. § 120. As previously set forth, perusal of the applications relied upon demonstrates that U.S. Serial No. 09/006,678, filed 13 January, 1998, and Provisional application 60/047,226, filed 20 May, 1997, fail to provide adequate support for the claimed invention. Neither of these applications discloses virus-like particles comprising generic multiple membrane spanning proteins. The '678 and '226 applications are clearly directed toward virus vectors comprising cellular virus receptor proteins that are cognate to a retroviral envelope protein. Although two of the disclosed cellular virus receptor proteins were also multiple membrane spanning proteins (e.g., CCR5 and CXCR4), nevertheless, there was no discussion of virus-like particles simply comprising multiple membrane spanning proteins, particularly those that are not necessarily cellular

virus receptor proteins. Moreover, the earlier filed applications fail to disclose the multiple membrane spanning proteins CXCR2, CXCR3, mu-opoid receptor, and KCNH2 potassium channel protein. The only discussion in these earlier applications is clearly directed toward cellular virus receptor proteins (see p. 6). Accordingly, for the purposes of applying prior art, those claims directed toward the aforementioned generic aspects (claims 1, 2, and 5-8), or species not previously recited, have been afforded an effective filing date of 22 December, 2000 (Provisional application 60/257,988).

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, and 5-8 stand rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Hoffman et al. (2000). Hoffman and colleagues provide virus-like particles comprising an enveloped virus core and heterologous multiple membrane spanning domain protein (e.g., CCR5, CXCR4) (see Figure 1, p. 11216). This teaching meets all of the claimed limitations.

Claims 1, 2, and 5-7 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Hunt (2001). Hunt discloses virus-like particles (VLPs) comprising an enveloped virus core and a

Application No.: 10/032,311
Applicants: Doms, R. W, et al.

Docket No.: 53893-5012-01
Filing Date: 12/21/2001

heterologous multiple membrane spanning domain protein (e.g., human Endothelin A receptor or ET_A). This teaching meets all of the claimed limitations.

Response to Arguments

Applicants traverse and submit that the priority applications relied upon adequately describe the claimed invention and that the examiner has employed the wrong legal standard. *In re Rasmussen*, 650 F.2d 1212, 1215 (C.C.P.A. 1981), and *Lampi Corp. v. American Power Products, Inc.*, 228 F.3d 1365, 1378 (Fed. Cir. 2000), were also relied upon in support of this argument. Applicants particularly rely upon *Lampi* asserting that the fact pattern is particularly relevant to the claimed invention.

Contrary to Applicants' assertions, the Examiner has applied the appropriate legal standard. As Applicants note, the correct legal standard is whether the claimed subject matter is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Smythe*, 480 F.2d 1376, 1384 (C.C.P.A. 1973). As previously set forth, perusal of the applications relied upon demonstrates that U.S. Serial No. 09/006,678, filed 13 January, 1998, and Provisional application 60/047,226, filed 20 May, 1997, fail to provide adequate support for the claimed invention. Neither of these applications discloses virus-like particles comprising generic multiple membrane spanning proteins. The '678 and '226 applications are clearly directed toward virus vectors comprising cellular virus receptor proteins that are cognate to a retroviral envelope protein. Although two

Application No.: 10/032,311
Applicants: Doms, R. W, et al.

Docket No.: 53893-5012-01
Filing Date: 12/21/2001

of the disclosed cellular virus receptor proteins were also multiple membrane spanning proteins (e.g., CCR5 and CXCR4), nevertheless, there was no discussion of virus-like particles simply comprising multiple membrane spanning proteins, particularly those that are not necessarily cellular virus receptor proteins. Moreover, the earlier filed applications fail to disclose the multiple membrane spanning proteins CXCR2, CXCR3, mu-opoid receptor, and KCNH2 potassium channel protein. The only discussion in these earlier applications is clearly directed toward cellular virus receptor proteins (see p. 6). Thus, the earlier filed applications would lead the skilled artisan to reasonably conclude that Applicants were interested primarily in targeting VLPs encoding viral receptors/coreceptors to infected cell targets. The earlier filed applications are silent with respect to the more generic concept of VLPs encoding any multiple membrane spanning domain protein, particularly those that are unrelated to viral replication and infectivity (e.g., G-protein coupled receptors, ion channel proteins, or transporter proteins).

Moreover, the reliance on *In re Rasmussen* and *Lampi Corp* fails to support Applicants' position because of the varying fact pattern in the instant application. The claims in *Rasmussen* were directed toward adherence methods and are not germane to the instantly claimed invention. The claims in *Lampi* are also not particularly relevant since they are directed toward identical and non-identical half shells. The fact pattern in the instant application differs considerably from the patterns set forth in the decisions relied upon. The earlier filed applications relied upon are clearly directed toward solving a

Application No.: 10/032,311

Docket No.: 53893-5012-01

Applicants: Doms, R. W, et al.

Filing Date: 12/21/2001

specific problem (targeting VLPs to infected cells) and essentially disclose a subgeneric concept and subspecies (e.g., VLPs encoding CD4/CCR5 or CD4/CXCR5) whereas the instant claims are directed toward totally different subgeneric concepts and subspecies (e.g., VLPs encoding the KCNH2 potassium channel protein or the μ -opioid receptor). These last two examples have absolutely nothing to do with targeting VLPs to virally-infected cells. Nothing in the earlier filed applications would reasonably lead the skilled artisan to conclude that applicants were thinking about these other scientific concepts.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Application No.: 10/032,311

Docket No.: 53893-5012-01

Applicants: Doms, R. W, et al.

Filing Date: 12/21/2001

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin/

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

17 February, 2009